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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,950	03/03/97	ASSMUS	M 583-252-0-FW

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15M2/1209

EXAMINER

SELLERS, R

ART UNIT	PAPER NUMBER
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1501

15

DATE MAILED:

12/09/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/813,950**

Applicant(s)  
**Assmus et al.**

Examiner  
**Robert Sellers**

Group Art Unit  
**1501**



☒ Responsive to communication(s) filed on Oct 22, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 3, 5, 7, 9, 11, 13, 15, and 17-24 is/are pending in the application.

Of the above, claim(s) 1, 3, 5, 7, 9, 11, 13, and 15 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 17-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's election with traverse of Group II in Paper No. 12 is acknowledged. The traversal is on the grounds that two-way distinctness necessary for a proper restriction has not been shown. This is not found persuasive because the criteria for demonstrating distinctness between a process of making a coated medicinal composition (Group I) and the coated product (Group II) is showing either that (1) the process can be used to make another and materially different product, or (2) the product can be made by another and materially different process, which has been indicated on page 2 of the Office action mailed September 2, 1997.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 1, 3, 5, 7, 9, 11, 13 and 15 drawn to an invention non-elected with traverse in Paper No. 12. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) MPEP § 821.01.

The 35 U.S.C. 112, first paragraph, rejection is resolved by the revelations on page 1, lines 16-18 and page 17, lines 22-26 of the specification that the coating and binder is applied to the medicinal compositions as a melt liquid.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Patent No. 2,082,573 (an equivalent of German Patent No. 4,138,513) and European Patent No. 204,596.

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Moest and Japanese Patent No. 57-169427 are withdrawn since the claimed application of the coating and binder as a hot-melt liquid excludes the coating of aqueous dispersions recited therein. Otherwise, the rejection is maintained for the reasons of record set forth in the previous Office actions. The arguments filed September 2, 1997 have been considered but are deemed to be unpersuasive.

The Canadian patent (page 4, lines 33-34, polyethylene glycol) and the European patent (page 4, lines 12-13 and page 11, Table II, Example 17, Precirol which is a fatty acid mono-, di- or triglyceride) show compounds identified as flow improvers on page 13, lines 8, 15 and 16 of the specification in amounts of from 10-40% by weight (European patent, page 4, last two lines). Accordingly, based on the equivalent types and proportions of Eudragit acrylic copolymers and polyethylene glycol or mono-, di- or triglycerides found in the references, no distinction is seen in the claimed non-homogeneity.

Page 4, lines 16-18 of the European patent describes the solubilization or gelling capacity of the lipid excipient (i.e. the mono-, di- or triglycerides) prior to melt extrusion. Due to concentrations and species of Eudragit acrylic copolymer and mono-, di- or triglycerides of the patent equivalent to those claimed, it is a matter of ordinary skill in the art that the compositions of the European patent as well as the Canadian patent would exhibit the claimed non-homogeneity once the mixture has solidified (Specification, page 7, lines 5-7).

The molecular weight of the flow improver would be more concisely defined if the weight average basis is inserted into claim 1 (Specification, page 6, lines 9-11).

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Robert Sellers at telephone number (703) 308-2399 (Fax nos. (703) 305-(5408 or 5433)).



**ROBERT E. SELLERS**  
**PRIMARY EXAMINER**  
**GROUP 150**

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12/5/97